



UNITED STATES PATENT AND TRADEMARK OFFICE

Exhibit A

V
Lx

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

(SUB) / JP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,223	08/22/2006	Herbert E. Schwartz	3124.006A	1470

23405 7590 01/05/2010
HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

LEVINE, JOSHUA H

ART UNIT PAPER NUMBER

3774

MAIL DATE DELIVERY MODE

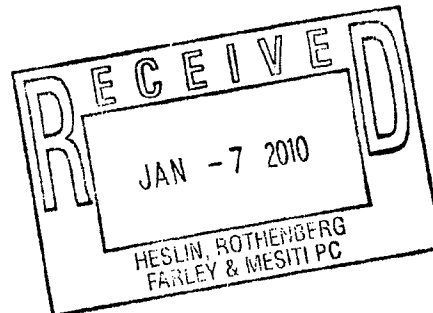
01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DOCKETED 4/5/10



Office Action Summary	Application No. 10/598,223	Applicant(s) SCHWARTZ, HERBERT E.	
	Examiner JOSHUA LEVINE	Art Unit 3774	
	-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 14 December 2009.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 35,36,38-43,45-49 and 51-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 35,36,38-43,45-49 and 51-57 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on 12/14/2009. As directed by the amendment: claims 35-36, 38, 40, 43, 51 and 54 have been amended, claims 1-34, 37, 44 and 50 have been cancelled, and new claims 56-57 have been added. Thus, claims 35-36, 38-43, 45-49, 51-57 are presently pending in this application.

Response to Arguments

2. Applicant's arguments filed 12/14/2009 have been fully considered but they are not persuasive.

The applicant argues that Hayhurst disclosed sutures simply **connected** to a cartilage material and not **attached** to the cartilage material and that an attached suture would render Hayhurst unworkable as intended. The examiner affirms the rejection as Hayhurst disclosed that the suture is held fast to the cartilage material via flaps 71 that act to wedge the suture into the retainer to hold the surface of cartilage in place (column 8 lines 6-10). Such an attachment allows the implant to remain workable as the suture can still slide under applied tension. Furthermore, the claim language "adapted to/for" and "configured to/for" is functional language and therefore, has been considered to the extent that the language further limits the structure of the components. For further explanations concerning functional language, see MPEP section 2114. See also MPEP section 703.03(c). A functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In re

Art Unit: 3774

Fuller, 1929 C.D. 172; 388 O.G. 279.

The applicant argues that the flexible member does not traverse through the cartilage replacement material multiple times as each segment traverses a material only once.

The examiner affirms the rejection as Hayhurst disclosed that each flexible member transverses the material multiple times as **each** of the two segments transverse the material at least once.

3. The applicant argues that the teachings of Hayhurst's implant are not combinable with the reference of Fallin as Hayhurst's anchor is not sufficiently relevant to the apparatus of Fallin. The examiner affirms the rejection as Hayhurst disclosed his invention to be applicable to both soft tissue anchors (between cartilage 76/78 and muscle 79, see fig 14), like that of Fallin, as well as bone anchors (tissue 99 and bone 96, figure 17). Moreover, The secondary reference of Fallin is not relied upon for the limitations of the biocompatible anchor shaped to fit with the defect site, retaining replacement material in the defect site, and retaining a piece of cartilage. These limitations are disclosed by the primary reference of Hayhurst.

The applicant argues that the loop of Fallin is not a sliding device as it does not provide any type of sliding along a suture to retain replacement material. The examiner affirms the rejection as Fallin teaches that free end 92 (figure 7) slides inside loop 88 by pulling on the free end 92 of the suture (column 6 lines 43-44).

The applicant argues that Fallin does not teach a sliding device that is a slipknot that when tensioned retains cartilage replacement material in a defect site. This limitation is considered functional language as the instant claim is drawn to an apparatus and not a

method. As such, the implant of Hayhurst in combination with Fallin is capable of acting in such a manner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 35-36, 38, 43, 45-47, 49, and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (5647874) in further view Fallin et al. (6972027).

6. Regarding claims 35-36, 38, 46-47 and 54, Hayhurst disclosed all the elements of the claim including a biocompatible anchor 110 (figure 19) shaped to site within tissue at the defect site and retain a section of cartilage replacement material 98 (figure 17) in the defect site as shown in figure 17, a biocompatible flexible member 118 (figure 19) traversing through said section of cartilage replacement material multiple times (column 10 lines 18-21), said flexible member being configured to attach to said section of replacement material at an attachment point 68 (figure 17), except for the flexible member threaded twice through the anchor to form at least two pulley mechanisms. Fallin teaches an anchor 56 (figure 7) with a flexible member 60 (figure 7) threaded through said anchor at least twice to form at least two pulley mechanisms and a slidable device 88 about said flexible member as shown in figure 7. The loop one starts at passageway 68A (figure 7) and ends at passageway 68B (figure 7). The second loop is between passageways 68B and passageway 68C. The opposite end 84 (figure 7) of

Art Unit: 3774

said flexible member is looped around said flexible member 60 to form a sliding device 88 (figure 7) for adjusting said distance between attachment point 58 (figure 7) and said anchor. The sliding device is a slipknot fashioned around flexible member 60 (figure 7). A slipknot is a knot that can easily be made tighter or looser by pulling one of its ends (Cambridge Advanced Learners Dictionary). Knot 88 can be made tighter by tensioning free end 92 (figure 7, column 6 lines 43-44). Therefore, It would have been obvious to one of ordinary skill in the art at the time of the invention to include the two loops and the knots, as suggested and taught by Fallin, for the purpose of creating loops and knots that allow slack in the flexible member for easy placement of the anchors as well as a mechanism to retract the slack in order to sufficiently tightly close tears to ensure proper healing (column 8 lines 28-323, column 8 lines 38-41).

7. Regarding claim 43, 45 and 49-50, Fallin teaches a flexible member that further comprises a stopping member 88 (figure 15 column 6 lines 41-48), said stopping member engageable with said section of cartilage replacement material where the stopping device is a slipknot. It would be obvious to one of ordinary skill in the art at the time of the invention to include the stopping member in order to create a device that allows for a sufficiently tight closure of the cartilage replacement material to the bone to ensure proper healing.

8. Regarding claim 55, Hayhurst disclosed wherein the section of cartilage replacement material comprises a scaffold 99 (tissue, figure 18), the scaffold being fabricated from a biocompatible material, tissue being capable of facilitating at least one of chondral and osteochondral integration.

Art Unit: 3774

9. Regarding claim 56, Hayhurst disclosed wherein the device further comprises the section of cartilage replacement material 98 (unattached tissue, figure 17, cartilage column 1 line 16).

10. Regarding claim 57, Hayhurst disclosed wherein the sliding device comprises a lockable sliding device 88 (loop, figure 7; securely locks suture 60 to anchor, column 8 lines 58-60).

11. Claims 39-41, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (5647874) in further view Fallin et al. (6972027) in further view of Binette et al (PG Pub no. 20050113937). Binette teaches a section of cartilage replacement material that is formed at least in part of a material selected from the group consisting of polyethylene and chitosan (paragraph 42). It would be obvious to one of ordinary skill in the art at the time of the invention to include these materials, as suggested and taught by Binette, for the purpose of facilitating cohesion of tissue fragments to allow an implant to take a semi-solid form allowing it to be cured into a solid implant.

12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (5647874) in further view Fallin et al. (6972027) in further view of Wolf et al (PG Pub no. 20040267314). Wolf teaches a flexible member that is a braided suture (paragraph 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the braided sutures, as suggested and taught by Wolf, for the purpose of allowing more flexibility to maneuver in surgical applications while adding tensile strength to the suture (paragraph 22).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. This is a request for continued examination of applicant's earlier Application No. 10598223. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

Application/Control Number: 10/598,223
Art Unit: 3774

Page 8

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOSHUA LEVINE/
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774